Reprinted
February 26, 2003

SENATE BILL No. 507

DIGEST OF SB 507 (Updated February 25, 2003 2:47 PM - DI 104)

Citations Affected: IC 12-8; IC 16-28; IC 25-26; IC 34-30.

Synopsis: Distribution of unused drugs. Allows a pharmacy or pharmacist to donate medications to certain health clinics. Establishes the regional drug repository program to distribute donated drugs. Requires a health facility to return unused medication that meets specified requirements to the pharmacy that dispensed the medication. Allows a pharmacy or pharmacist to accept returned medications from a hospice program. Requires the office of Medicaid policy and planning to review the process of returning unused medication.

Effective: July 1, 2003.

Dillon, Breaux, Skinner, Dembowski

January 23, 2003, read first time and referred to Committee on Health and Provider Services.
February 13, 2003, amended, reported favorably — Do Pass.
February 25, 2003, read second time, amended, ordered engrossed.

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First Regular Session 113th General Assembly (2003)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2002 Regular or Special Session of the General Assembly.

SENATE BILL No. 507

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 12-8-6-6.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: **Sec. 6.5. (a) Before December 31, 2003, the office shall review the process of returning unused medication under IC 25-26-13-25 and the process of reimbursing the office for unused medication of a Medicaid recipient. The office may consider in the office's review information provided by long term care pharmacies. Beginning December 31, 2003, the office may review the process of returning unused medication when the office determines that a review is necessary.**

(c) After the office conducts a review under subsection (a), the office may adopt rules under IC 4-22-2 to require a pharmacist to accept medication for return under IC 25-26-13-25. The rules adopted by the office may include compensation to the pharmacist for the return of medication under IC 25-13-25.

SECTION 2. IC 16-28-11-4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY

1, 2003]: **Sec. 4. A health facility that possesses unused medication that meets the requirements of IC 25-26-14-25(i)(1) through IC 25-26-14-25(i)(6):**

(1) shall return medication that belonged to a Medicaid recipient; and

(2) may return other unused medication;

to the pharmacy that dispensed the medication.

SECTION 3. IC 25-26-13-25, AS AMENDED BY P.L.1-2002, SECTION 98, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 25. (a) All original prescriptions, whether in written or electronic format, shall be numbered and maintained in numerical and chronological order, or in a manner approved by the board and accessible for at least two (2) years in the pharmacy. A prescription transmitted from a practitioner by means of communication other than writing must immediately be reduced to writing or recorded in an electronic format by the pharmacist. The files shall be open for inspection to any member of the board or its duly authorized agent or representative.

(b) Except as provided in subsection (c) before the expiration of subsection (c) on June 30, 2003, a prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may not be refilled without written or oral authorization of a licensed practitioner.

(c) A prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may be refilled by a pharmacist one (1) time without the written or oral authorization of a licensed practitioner if all of the following conditions are met:

(1) The pharmacist has made every reasonable effort to contact the original prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(2) The pharmacist believes that, under the circumstances, failure to provide a refill would be seriously detrimental to the patient's health.

(3) The original prescription authorized a refill but a refill would otherwise be invalid for either of the following reasons:

(A) All of the authorized refills have been dispensed.

(B) The prescription has expired under subsection (f).

(4) The prescription for which the patient requests the refill was:

(A) originally filled at the pharmacy where the request for a refill is received and the prescription has not been transferred for refills to another pharmacy at any time; or

(B) filled at or transferred to another location of the same pharmacy or its affiliate owned by the same parent corporation if the pharmacy filling the prescription has full access to prescription and patient profile information that is simultaneously and continuously updated on the parent corporation's information system.

(5) The drug is prescribed for continuous and uninterrupted use and the pharmacist determines that the drug is being taken properly in accordance with IC 25-26-16.

(6) The pharmacist shall document the following information regarding the refill:

(A) The information required for any refill dispensed under subsection (d).

(B) The dates and times that the pharmacist attempted to contact the prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(C) The fact that the pharmacist dispensed the refill without the authorization of a licensed practitioner.

(7) The pharmacist notifies the original prescribing practitioner of the refill and the reason for the refill by the practitioner's next business day after the refill has been made by the pharmacist.

(8) Any pharmacist initiated refill under this subsection may not be for more than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day. However, a pharmacist may dispense a drug in an amount greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day if:

(A) the drug is packaged in a form that requires the pharmacist to dispense the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day; or

(B) the pharmacist documents in the patient's record the amount of the drug dispensed and a compelling reason for dispensing the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day.

(9) Not more than one (1) pharmacist initiated refill is dispensed under this subsection for a single prescription.

(10) The drug prescribed is not a controlled substance.

A pharmacist may not refill a prescription under this subsection if the practitioner has designated on the prescription form the words "No

Emergency Refill". This subsection expires June 30, 2003.

(d) When refilling a prescription, the refill record shall include:

(1) the date of the refill;

(2) the quantity dispensed if other than the original quantity; and

(3) the dispenser's identity on:

(A) the original prescription form; or

(B) another board approved, uniformly maintained, readily retrievable record.

(e) The original prescription form or the other board approved record described in subsection (d) must indicate by the number of the original prescription the following information:

(1) The name and dosage form of the drug.

(2) The date of each refill.

(3) The quantity dispensed.

(4) The identity of the pharmacist who dispensed the refill.

(5) The total number of refills for that prescription.

(f) A prescription is valid for not more than one (1) year after the original date of issue.

(g) A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

(h) A pharmacist may not knowingly dispense a prescription after the demise of the patient.

(i) A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

(1) was dispensed to a patient:

(A) residing in an institutional facility (as defined in 856 IAC 1-28-1(a)); **or**

(B) in a hospice program under IC 16-25;

(2) was properly stored and securely maintained according to sound pharmacy practices;

(3) is returned unopened and:

(A) was dispensed in the manufacturer's original:

(i) bulk, multiple dose container with an unbroken tamper resistant seal; or

(ii) unit dose package; or

(B) was packaged by the dispensing pharmacy in a:

(i) multiple dose blister container; or

(ii) unit dose package;

(4) was dispensed by the same pharmacy as the pharmacy accepting the return;

(5) is not expired; and

(6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Type II permit (as described in IC 25-26-13-17).

(j) A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under subsection ~~(h).~~ **(i). A state agency may require a pharmacist to accept the medication unless the acceptance of the medication would violate the pharmacist's professional judgment.**

(k) A pharmacist who violates subsection (c) commits a Class A infraction.

SECTION 4. IC 25-26-19 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]:

Chapter 19. Regional Drug Repository Program

Sec. 1. The definitions in IC 25-26-13-2 apply throughout this chapter.

Sec. 2. As used in this chapter, "nonprofit health clinic" means the following:

(1) A federally qualified health center (as defined in 42 U.S.C. 1396d(l)(2)(B)).

(2) A rural health clinic (as defined in 42 U.S.C. 1396d(l)(1)).

(3) A nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured.

Sec. 3. (a) The board may organize a voluntary regional drug repository program to collect and redistribute drugs to nonprofit health clinics.

(b) The board may enter into a voluntary agreement with any of the following to serve as a regional drug repository:

(1) A pharmacist or pharmacy.

(2) A drug manufacturer.

(3) A wholesale drug distributor.

(4) A hospital.

(5) A health care facility.

(6) A nonprofit health clinic.

(c) A regional drug repository must hold a controlled substances registration issued under IC 35-48-3.

(d) A regional drug repository may not receive compensation for participation in the program.

Sec. 4. Unadulterated drugs, including a medication that has been returned under IC 25-26-13-25(i), may be donated without a prescription or drug order to the regional drug repository

program by the following:

(1) A pharmacist or pharmacy.

(2) A drug manufacturer.

(3) A wholesale drug distributor.

(4) A hospital.

(5) A health care facility.

(6) A hospice.

(7) A practitioner.

Sec. 5. A drug that is given by a regional drug repository to a nonprofit health clinic may not be:

(1) sold; or

(2) given to a patient except upon a practitioner's prescription or drug order.

Sec. 6. (a) Except in cases of bad faith or willful misconduct, any person, including a drug manufacturer, that donates a drug to the regional drug repository program and any nonprofit health clinic or practitioner who accepts or dispenses drugs under the program is not:

(1) subject to disciplinary actions; or

(2) liable for civil or criminal actions for the injury, death, or loss to a patient;

for matters related to the donation, acceptance, or dispensing of a drug under the program.

(b) Except in cases of bad faith or willful misconduct, a drug manufacturer is not liable for civil or criminal actions for any drug that was made by the drug manufacturer concerning the failure to transfer or communicate product or consumer information or the expiration date of the drug donated under the program.

(c) Except in cases of bad faith or willful misconduct, a regional drug repository is not liable for civil or criminal actions for the injury, death, or loss to a patient related to the donation, acceptance, or dispensing of a drug under the program.

Sec. 7. The board may adopt rules under IC 4-22-2 to:

(1) establish standards and procedures for accepting, storing, and dispensing drugs donated under this chapter;

(2) establish the types of drugs that may be donated; and

(3) administer this chapter.

SECTION 5. IC 34-30-2-101.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: **Sec. 101.5. IC 25-26-19-6 (Concerning drugs donated to a regional drug repository program).**

SENATE MOTION

Mr. President: I move that Senator Breaux be added as second author and Senator Skinner be added as coauthor of Senate Bill 507.

DILLON

COMMITTEE REPORT

Mr. President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 507, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 16-28-11-4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: **Sec. 4. A health facility that possesses unused medication that meets the requirements of IC 25-26-14-25(i)(1) through IC 25-26-14-25(i)(6) shall return the medication to the pharmacy that dispensed the medication.**".

Page 4, line 23, strike "may use the pharmacist's professional judgment as".

Page 4, line 24, strike "to whether to" and insert "**shall**".

Page 4, line 24, delete "(i)." and insert "**(i) if the medication meets the requirements set forth in this section. If the prescription drug was paid for by the state Medicaid program, the pharmacy shall submit an adjustment form to the office in the manner prescribed by the office of Medicaid policy and planning to credit the state Medicaid program for the cost of the prescription drug.**".

Page 4, delete lines 27 through 42, begin a new paragraph and insert:

"SECTION 2. IC 25-26-19 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]:

Chapter 19. Regional Drug Repository Program

Sec. 1. The definitions in IC 25-26-13-2 apply throughout this chapter.

Sec. 2. As used in this chapter, "nonprofit health clinic" means the following:

(1) A federally qualified health center (as defined in 42 U.S.C. 1396d(l)(2)(B)).

(2) A rural health clinic (as defined in 42 U.S.C. 1396d(l)(1)).

(3) A nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured.

Sec. 3. (a) The board may organize a voluntary regional drug repository program to collect and redistribute drugs to nonprofit health clinics.

(b) The board may enter into a voluntary agreement with any

of the following to serve as a regional drug repository:

(1) A pharmacist or pharmacy.

(2) A drug manufacturer.

(3) A wholesale drug distributor.

(4) A hospital.

(5) A health care facility.

(6) A nonprofit health clinic.

(c) A regional drug repository must hold a controlled substances registration issued under IC 35-48-3.

(d) A regional drug repository may not receive compensation for participation in the program.

Sec. 4. Unadulterated drugs, including a medication that has been returned under IC 25-26-13-25(i), may be donated without a prescription or drug order to the regional drug repository program by the following:

(1) A pharmacist or pharmacy.

(2) A drug manufacturer.

(3) A wholesale drug distributor.

(4) A hospital.

(5) A health care facility.

(6) A hospice.

(7) A practitioner.

Sec. 5. A drug that is given by a regional drug repository to a nonprofit health clinic may not be:

(1) sold; or

(2) given to a patient except upon a practitioner's prescription or drug order.

Sec. 6. (a) Except in cases of bad faith or willful misconduct, any person, including a drug manufacturer, that donates a drug to the regional drug repository program and any nonprofit health clinic or practitioner who accepts or dispenses drugs under the program is not:

(1) subject to disciplinary actions; or

(2) liable for civil or criminal actions for the injury, death, or loss to a patient;

for matters related to the donation, acceptance, or dispensing of a drug under the program.

(b) Except in cases of bad faith or willful misconduct, a drug manufacturer is not liable for civil or criminal actions for any drug that was made by the drug manufacturer concerning the failure to transfer or communicate product or consumer information or the expiration date of the drug donated under the program.

(c) Except in cases of bad faith or willful misconduct, a regional drug repository is not liable for civil or criminal actions for the injury, death, or loss to a patient related to the donation, acceptance, or dispensing of a drug under the program.

Sec. 7. The board may adopt rules under IC 4-22-2 to:

(1) establish standards and procedures for accepting, storing, and dispensing drugs donated under this chapter;

(2) establish the types of drugs that may be donated; and

(3) administer this chapter.

SECTION 3. IC 34-30-2-101.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: **Sec. 101.5. IC 25-26-19-6 (Concerning drugs donated to a regional drug repository program).**".

Page 5, delete lines 1 through 2.

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 507 as introduced.)

MILLER, Chairperson

Committee Vote: Yeas 10, Nays 0.

SENATE MOTION

Mr. President: I move that Senator Dembowski be added as coauthor of Senate Bill 507.

DILLON

SENATE MOTION

Mr. President: I move that Senate Bill 507 be amended to read as follows:

Page 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 12-8-6-6.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: **Sec. 6.5. (a) Before December 31, 2003, the office shall review the process of returning unused medication under IC 25-26-13-25 and the process of reimbursing the office for unused medication of a Medicaid recipient. The office may consider in the office's review information provided by long term care pharmacies. Beginning December 31, 2003, the office may review the process of returning unused medication when the office determines that a review is necessary.**

(c) After the office conducts a review under subsection (a), the office may adopt rules under IC 4-22-2 to require a pharmacist to accept medication for return under IC 25-26-13-25. The rules adopted by the office may include compensation to the pharmacist for the return of medication under IC 25-13-25.".

Page 1, line 5, after "IC 25-26-14-25(i)(6)" insert "**:**

(1)."

Page 1, line 5, after "return" delete "the".

Page 1, line 5, after "medication" insert "**that belonged to a Medicaid recipient; and**

(2) may return other unused medication; ".

Page 1, line 5, beginning with "to" begin a new line blocked left.

Page 4, line 29, reset in roman "may use the pharmacist's professional judgment as".

Page 4, line 30, reset in roman "to whether to".

Page 4, line 30, delete "shall".

Page 4, line 31, delete "(i) if the medication meets the requirements set forth in this" and insert "**(i). A state agency may require a pharmacist to accept the medication unless the acceptance of the**

medication would violate the pharmacist's professional judgment.".

Page 4, delete lines 32 through 36.

Renumber all SECTIONS consecutively.

(Reference is to SB 507 as printed February 14, 2003.)

DILLON